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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,215	10/30/2001	Grant L. Schoenhard	13727US01 4991	
7590 01/15/2004			EXAMINER	
Janet M. McNicholas, Ph.D. McAndrews, Held & Malloy, Ltd. Suite 3400 500 West Madison Street Chicago, IL 60661			JAGOE, DONNA A	
			ART UNIT	PAPER NUMBER
			1614	
			DATE MAILED: 01/15/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
		10/003,215	SCHOENHARD, GRANT L.				
Office Action Summary		Examiner	Art Unit				
		Donna Jagoe	1614				
Period fo	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply secified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status	<b>-</b>						
	Responsive to communication(s) filed on	-					
·		action is non-final.					
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4)	Claim(s) is/are pending in the application	1.					
	4a) Of the above claim(s) is/are withdrawn from consideration.						
	5) Claim(s) is/are allowed.						
	6) Claim(s) <u>28-33</u> is/are rejected.						
	Claim(s) is/are objected to.						
8)	8) Claim(s) are subject to restriction and/or election requirement.						
Applicati	on Papers						
	9)☐ The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. §§ 119 and 120							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No.  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application)							
since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.  37 CFR 1.78.  a)  The translation of the foreign language provisional application has been received.							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.							
Attachment(	(s)						
I)	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) 🔲 Notice of Informal Pate	TO-413) Paper No(s) ent Application (PTO-152)				
) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6) I Other: .							

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## Claims 28-33 are pending in this application.

### Response to Arguments

Applicant's arguments filed 20 October 2003 have been fully considered but they are not persuasive. The rejection made in the office action of April 18, 2003 over Broder et al. U.S. 5,968,972 under 35 U.S.C. §102(b) is maintained and is hereby repeated.

Applicant asserts that Broder does not suggest or teach that opioids such as naloxone, naltrexone and nalmefene are inhibitors of P-glycoprotein and also does not suggest or teach amounts of opioid inhibitors in the range of  $0.00001~\mu m$  to  $100~\mu m$ . In reply, these properties are considered to be inherent. Products of identical chemical composition (i.e. naloxone, naltrexone and nalmefene) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Further, it is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from prior art, can not impart patentability to claims to the known composition."); Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 782, 227 USPQ

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773, 778 (Fed. Cir. 1985) (composition claim reciting a newly discovered property of an old alloy did not satisfy section 102 because the alloy itself was not new); In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claim patentable); In re Zierden, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969) (" [M] ere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable."); In re Sinex, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim failed to distinguish over the prior art apparatus); In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 162 (CCPA 1957) ("the grant of a patent on a composition or a machine cannot be predicated on a new use of that machine or composition"); In re Benner, 174 F.2d 938, 942, 82 USPQ 49, 53 (CCPA 1949) ("no provision has been made in the patent statutes for granting a patent upon an old product based solely upon discovery of a new use for such product"). Regarding the limitation added with the amendment of 10/20/03, it would be inherent upon the administration of a pharmaceutically effective dose of the anti-tumor compound as taught by the prior art.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3230.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Donna Jagoe Patent Examiner Art Unit 1614

Frederick Krass Primary Examiner

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